SEP 2 1 2009

K090718

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

Company:.....3M ESPE AG
Street:.....ESPE Platz
ZIP-Code, City:.....D-82229 Seefeld
Federal State:.....Bavaria
Country:.....Germany
Establishment Registration Number.....9611385
Official Correspondent:.....Dr. Desi W. Soegiarto,
.....Regulatory Affairs Specialist
Phone:.....011-49-8152-700 1169
Fax:.....011-49-8152-700 1869
E-mail:.....desi.soegiarto@mmm.com
Date:.....March 13, 2009

Name of Device

Proprietary Name:.....Bellus Shading Kit

Classification Name:.....Porcelain powder for clinical use

Common Name:.....Colors, stains, shades, glaze

Predicate Device

IPS Empress Universal Shade/Stains.....Presumably K980986
by Ivoclar Vivadent
Glass Ceramics "Jolly" by 3M ESPE.....K053438
Lava Ceram by 3M ESPE.....K011394
Position Penta by 3M ESPE.....K974231

Description for the Premarket Notification

Bellus Shading Kit is classified as Porcelain powder for clinical use (21 C.F.R. § 872.6660). Bellus Shading Kit is intended to be used for color staining and glazing of glass ceramic restorations made from 3M ESPE's Glass Ceramics "Jolly" (K053438).

Bellus Shading Kit contains stain pastes, a glazing paste, and a liquid which can be used to thin the pastes. The pastes serve solely for the color staining and glazing of the surfaces of restorations made from "Jolly" glass ceramic blocks, manufactured for 3M ESPE.

To provide evidence for safety biocompatibility testing was carried out. The results show that Bellus Shading Kit is a safe device.

The comparison for chemistry, performance data and indications for use shows that Bellus Shading Kit is substantially equivalent to the predicate devices.

In summary, it can be concluded that safety and effectiveness requirements for Bellus Shading Kit are completely met.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 21 2009

Dr. Desi W. Soegiarto
Regulatory Affairs Specialist
3M ESPE AG Dental Products
ESPE Platz
Seefeld, Bavaria
GERMANY D-82229

Re: K090718
Trade/Device Name: Bellus Shading Kit
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: August 27, 2009
Received: August 31, 2009

Dear Dr. Soegiarto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090718

Indications for Use

510(k) Number (if known):	K090718
Device Name:	Bellus Shading Kit
Indications For Use:	Color staining and glazing of glass ceramic restorations made from 3M ESPE's Glass Ceramics "Jolly".

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulvey for M&R

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090718

Page 1 of _____